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10/780,267	02/17/2004	Donald Lynn Bissett	9176R	2224

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EXAMINER	
OLSON, ERIC	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,267	BISSETT, DONALD LYNN	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22,24-26 and 28-36* is/are pending in the application.

4a) Of the above claim(s) *6-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,21,22,24-26 and 28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted January 8, 2008 wherein claims 1 and 24-26 are amended and claims 2 and 23 are cancelled. This application is a continuation in part of US application 10/379252, now abandoned, filed March 4, 2003.

Claims 1, 3-22, 24-26, and 28-36 are pending in this application.

Claims 1, 3-5, 21, 22, 24-26, and 28-36 as amended are examined on the merits herein.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 24, 26, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Warren et al. (US pre-grant publication 2003/0082219, cited in PTO-892)

Warren et al. discloses skin care compositions comprising hexamidine, zinc oxide, niacinamide, and a carrier. (p. 1 paragraph 0008) Specific compositions are disclosed having 0.1% or 0.05% hexamidine and 1% or 2% niacinamide, as well as

between 0.2-7% zinc oxide and 0.25% or 0.5% panthenol. (p. 10 left column table 2) The compositions are useful for treating microbial skin infections. (p. 3 paragraphs 0023-0024) Note that zinc oxide is an antimicrobial active and a sunscreen active. Warren et al. also discloses using proteins in the disclosed compositions. (paragraph 0035) Vitamin C (an antioxidant) can also be included (p. 4 paragraphs 0034-0035) Therefore Warren et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 5, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. US pre-grant publication 2003/0082219, cited in PTO-892) as applied to claims 1, 3, 24, 26, and 32 above, and further in view of Wright. (US patent 5547577, cited in PTO-892)

The disclosure of Warren et al. is discussed above. Warren et al. does not disclose an emulsion or a composition comprising a phytosterol.

Wright discloses a stable antimicrobial oil-in-water emulsion comprising a water phase and an oil phase, and additionally containing a sterol such as a phytosterol. (column 2 lines 10-24) These antimicrobial compositions can be administered to the skin to inhibit the growth of an infections pathogen. (column 2 lines 25-40)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the ingredients described by Warren et al., for example hexamidine, niacinamide, zinc oxide, and panthenol, to an antimicrobial emulsion containing a phytosterol as described by Wright. One of ordinary skill in the art would have been motivated to make this combination because both compositions are described as being useful for the same purpose, namely inhibiting microbial growth on the skin. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. US pre-grant publication 2003/0082219, cited in PTO-892) as applied to claims 1, 3, 24, 26, and 32 above, and further in view of Stuttgen et al. (US patent 5547577, cited in PTO-892)

The disclosure of Warren et al. is discussed above. Warren et al. additionally discloses that antimicrobial agents can be used to treat acne. (p. 1 paragraph 0003) Warren et al. does not disclose a composition comprising caffeine.

Stuttgen et al. discloses a gel for the treatment of acne comprising caffeine and sodium alpha-estradiol sulfate. (column 6 lines 35-40)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the ingredients described by Warren et al., for example hexamidine, niacinamide, zinc oxide, and panthenol, with caffeine and sodium alpha-estradiol for the treatment of acne. One of ordinary skill in the art would have been motivated to make this combination because both compositions are described as being useful for the same purpose, namely treating acne. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. US pre-grant publication 2003/0082219, cited in PTO-892) as applied to claims 1, 3, 24, 26, and 32 above, and further in view of Stack. (US patent 6187327, cited in PTO-892)

The disclosure of Warren et al. is discussed above. Warren et al. additionally discloses that the disclosed compositions can include skin conditioning agents. (p. 4 paragraph 0035) Warren et al. does not disclose a composition comprising tocopherol acetate.

Stack discloses an antimicrobial hand sanitizing lotion. (column 2 lines 64-67) Tocopherol acetate is listed as an ingredient that can be added in order to provide skin conditioning properties. (column 7 lines 33-39)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the ingredients described by Warren et al., for example hexamidine, niacinamide, zinc oxide, and panthenol, with tocopherol acetate. One of ordinary skill in the art would have been motivated to make this combination because Stack discloses that tocopherol acetate is useful as a skin conditioning agent in antimicrobial compositions. One of ordinary skill in the art would reasonably have expected success because Warren et al. already discloses using conditioning agents in these compositions.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. US pre-grant publication 2003/0082219, cited in PTO-892) as applied to claims 1, 3, 24, 26, and 32 above, and further in view of Yu et al. (US patent 5091171, cited in PTO-892)

The disclosure of Warren et al. is discussed above. Warren et al. additionally discloses that antimicrobial agents can be used to treat acne. (p. 1 paragraph 0003) Warren et al. does not disclose a composition comprising carnosine.

Yu et al. discloses a composition comprising an alpha ketoacid and an amphoteric compound, that is useful for treating a variety of different conditions

including acne. (column 3 lines 3-30) The amino acid amphoterics include dipeptides such as carnosine. (column 5 lines 19-21)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the ingredients described by Warren et al., for example hexamidine, niacinamide, zinc oxide, and panthenol, with carnosine and an alpha ketoacid for the treatment of acne. One of ordinary skill in the art would have been motivated to make this combination because both compositions are described as being useful for the same purpose, namely treating acne. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Therefore the invention taken as a whole is *prima facie* obvious.

The following rejections of record in the previous action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 21, 23-24, 26 and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett et. al. (U.S. Patent No. 6,284,802; of record in previous action)

Bissett et. al. discloses the use of vitamin B3 compounds in skin care compositions. (Column 33, claim 3). Example 1 discloses a composition with 2% niacinamide, a vitamin B3 compound. (Column 30, lines 1-5; Column 16-17, section titled "Vitamin B3 compounds"). Water, glycerin and silicone fluids are disclosed in emulsions and are considered carriers. (Example 2). Hexamidine is disclosed as useful as an antimicrobial adduct. (Column 23, line 45-55). Bissett further discloses the use of anti-acne actives, peptides, scavengers and sunscreen additives. (Column 34, claim 6; See Column 16, section titled "Desquamation agents"; Column 18, titled "peptides"). Bissett further discloses ascorbyl glucosamine as an additive. (Column 15, lines 65-68). Glucosamine and panthenol are disclosed as a conditioning agents. (Column 25, lines 50-Column 26, line 5; Column 33, claim 4). Tocopherol acetate is disclosed as an anti-oxidant additive. (Column 19, lines 1-36). Retinoids (column 17 lines 39-65) peptides including carnosine (column 18 lines 27-42) anti-cellulite agents including caffeine (column 22 lines 42-47) and natural anti-inflammatory agents such as phytosterols. (column 22 lines 12-24) Example 4 in column 32 lines 15-40 includes butylated hydroxytoluene, which falls within the structure of new claim 36, as an ingredient.

Bissett does not exemplify a composition comprising hexamidine

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a skin care composition comprising hexamidine, and

vitamin B3 and additional ingredients such as peptides, additives claimed in claim 3, and tocopherol acetate since all ingredients are well known for their use in skin care preparations and useful for compositions for skin care as disclosed in Bissett et. al. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, one of ordinary skill in the art would have reasonably expected that a composition comprising hexamidine in combination with other cosmetic/skin care actives would have resulted in beneficial effects as a skin care composition.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted January 8, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the previously submitted declaration of Rosemarie Osborne is sufficient to demonstrate unexpected results because the *in vitro* model used in the disclosed results is an art-recognized model of human skin reaction to therapeutic agents. To support this position Applicant suggests several references including Ponec et al. and Weiss et al. (References included with PTO-892) However, these references, which concern the evaluation of skin irritation in *in vitro* systems, disclose multiple methods of assessing skin reactions, including cell viability, morphology, and expression of different biomarkers. Biomarkers which are

used to assess skin irritation include known markers of irritation and inflammation including interleukins, tumor necrosis factor, arachidonic acid metabolites, and calcium. Where new biomarkers are proposed, such as the heat shock protein HSP27 or the chemokine CCL27, they are proposed based on their observed differential expression in irritated tissues. The Osborne declaration, on the other hand, fishes out a collection of genes that in hindsight happen to be synergistically affected by hexamidine and vitamin B3 and speculates as to their possible correlation with beneficial morphological changes of the skin. It is a significant and unwarranted step to extrapolate from increased expression of genes involved in glucogenesis and RNA splicing to the panoply of morphological effects that Applicant suggests might result from these changes in gene expression, for example treating of fine lines, hyperpigmentation, sagging, dryness, and the like. While it is true that expression of certain genes, such as interleukins or tumor necrosis factor, is used in the art as a marker for certain morphological processes such as irritation, this correlation is based on an observed, direct correlation between expression of a gene and the effect being studied, as described by Weiss et al. and Ponec et al., rather than the general observation, in Declarant's words, that "glucose is a fundamental compound that is essential to processes that regulate the condition of mammalian keratinous tissues such as skin." None of the genes indicated in the declaration have actually been positively identified as correlating with a specific observable effect. Therefore the observation of changes in gene activation, in the absence of any evidence tying these genes to the desired biological effects, is not

persuasive to demonstrate unexpected results for a combination that activates these genes.

Applicant's remarks concerning the claimed ranges and the sufficiency of the declaration in demonstrating unexpected results over the claimed ranges are moot as the claims have been amended to recite narrower ranges and the declaration is not seen to disclose unexpected results over any ranges at all.

Applicant finally argues that the declaration proves that the combination of these two elements yields an unpredictable result because of the non-additive activation of certain genes. Without any clear evidence linking the changes in gene expression to a practical effect, this data does not demonstrate anything as to the actual practical effect of the composition, and cannot demonstrate any unpredictable results for said combination.

For these reasons the rejection is deemed proper and maintained.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett et. al. (U.S. Patent No. 6,284,802; of record in previous action) as applied to claims 1-5, 21, 23-24, 26 and 28-36 above, and further in view of Castiel et. al. (US 2003/0176366 A1, of record in previous action)

The disclosure of Bissett et al. is discussed above. Bissett et al. does not disclose a composition comprising ascorbyl glucoside.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1,

Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside. (Page 4, Column 2, Example 3) These compositions are useful for improving the suppleness and appearance of the skin, treating wrinkles and fine lines, and combating aging. (p. 3 paragraph 45)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add ascorbyl glucoside to the compositions of Bissett et al. One of ordinary skill in the art would have been motivated to do so because both compositions are disclosed to be useful for the same purpose, namely improving the appearance and quality of the skin. One of ordinary skill in the art would reasonably have expected success because combining two known prior art compositions is ordinary and routine for one of ordinary skill in the art.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted January 8, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Bissett et al. above and are not found persuasive for the same reasons. Therefore the rejection is deemed proper and maintained.

Claims 1, 3-5, 23, 24, 26, 28, 29, 31, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. (US patent 6589514, of record in previous action) in view of Flick et. al. (Cosmetic Additives - An industrial Guide, Pages 647-648,

652; Of record), Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

Jensen et. al. discloses compositions comprising hexamidine (0-1%), and carriers including water, seed oil and vegetable oil. The presence of water, fruit juice, glyceryl stearate, seed oil, vegetable oil and PEG-40 stearate is expected to form an emulsion in the form of a water-in-oil or oil-in-water or a combination of both.

Furthermore, Jensen et. al. discloses the use of panthenol in a skin care composition. Example two of Jensen (column 11, lines 35-68) is a dermatological composition including *Morifinda citrifola* fruit juice, the retinoid retinyl palmitate and BHT. *Morifinda citrifola* fruit juice is disclosed to comprise many different active agents including

Jensen et. al. does not expressly disclose a composition comprising vitamin B3 or panthenol in combination with a hexamidine compound and a carrier. (Column 11, Example 2, line 53-64).Jensen et. al. further discloses the use of tocopheryl acetate (Column 11, Example 2, line 58-60, Example 4, lines 43, Example 1).

Flick et. al. in his cosmetic handbook discloses that panthenol is used in skin care products as a quick deep penetrating moisturizer, that aids in tissue repair and promotes normal keratinization. (Cosmetic Additives- An Industrial Guide, Page 648, Paragraph titled "Role in skin care products"). Flick et. al. further discloses commercial sources of panthenol compounds. (Page .647). Flick et. al. further discloses commercial sources of various forms of vitamin E including a-tocopherol acetate. (Page 652) As

such, panthenol and a-tocopherol acetate are considered as ingredients well known by one of ordinary skill in the arts in the cosmetic, pharmaceutical and skin care industry.

Gensler HL et. al. discloses that topical nicotinamide (also known by the chemical name niacinamide) prevents the systemic immunosuppression and skin tumorgenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that immunoenhancement by nicotinamide results in prevention of phtocarcinogenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that e-tocopherol can also contribute to inhibition of photoimmunosuppression and photocarcinogenesis. (Page 161, Column 2, second paragraph). One or ordinary skill in the art would recognize protecting against UVB as a beneficial in a skin care composition.

Oblong et. al. discloses that vitamin B3 compounds can have beneficial effects such as improving tactile discontinuities of the skin. Oblong discloses the use of 2-5% niacinamide. (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, vitamin B3, panthenol, a-tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising a-tocopherol acetate, hexamidine and discloses panthenol in skin care compositions and Flick et. al. discloses panthenol and e-tocopherol acetate as commercially available cosmetic additives and Gensler et. al. discloses that topical application of niacinamide and a-tocopherol can contribute to protection against UVB rays and Oblong et. al. discloses the beneficial effects of

niacinamide such as regulating visible and tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and a-tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted January 8, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Gessler et al. discloses applying nicotinamide topically in acetone solution which is not a topically acceptable carrier. However, the use of various topically acceptable carriers, and the formulation of a known active ingredient in a known carrier, is well within the ordinary and routine level of skill in the art. As described by Remington (Reference included with PTO-892) which is taken as representing common knowledge in the art, various topical carriers for

ointments, creams, and lotions are known in the art which can be used to deliver a variety of topical active agents, and can be optimized for delivering a specific agent to treat a specific disease state. (p. 845 left column paragraphs 1-5) One of ordinary skill in the art would be able to undertake such a process of optimization to determine a suitable formulation base for delivering the claimed active agents. The motivation to do so is provided above as the various components are all known to be useful for topical administration for the same purpose. One of ordinary skill in the art would reasonably have expected success because this process of routine optimization is part of the ordinary and routine level of skill in the art. Those of ordinary skill in the pharmaceutical art routinely formulate useful active ingredients in dosage forms for delivery by different routes of delivery such as topical administration, without significant alterations to the active agent's function or efficacy that preclude its use in any topically acceptable carrier.

Applicant further argues that the declaration previously presented by Rosemarie Osborne demonstrates unexpected results for the claimed compositions of vitamin B3 and hexamidine. This argument is the same as the one made above with respect to the rejection over Bissett et al., and is not found to be persuasive for the same reasons.

Therefore the rejection is deemed proper and maintained.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Gensler et. al. (of record in previous action), Mammone et. al.

(WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

The disclosure of Jensen et. al. is disclosed above. Jensen et. al. does not expressly disclose the use of vitamin B3 compounds, in particular niacinamide or the use of N-acetyl glucosamine in skin care compositions. The disclosure of Gensler et. al. is discussed above.

Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions used for exfoliation and moisturization. (Abstract, Page 2, lines 14-17). The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, N-acetyl glucosamine, niacinamide and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine and Gensler et. al. discloses that topical application of niacinamide can contribute to inhibition of photoimmunosuppression and photocarcinogenesis and Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions as an exfoliant and Oblong discloses the use of niacinamide against tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said

ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and a-tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted January 8, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Jensen et. al. in view of Flick et. al. Gensler et. al. and Oblong et. al. above and are not found persuasive for the same reasons. Therefore the rejection is deemed proper and maintained.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Castiel et. al. (US 2003/0176366 A1, of record in previous action), (WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

The disclosure of Jensen et. al. is discussed above

Jensen et. al. does not expressly disclose the use of ascorbyl glucoside in skin care compositions or a 0.01 to 10% of a vitamin B3 compound.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1, Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside (Page 4, Column 2, Example 3).

The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, a retinoid, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, carriers and a retinoid and Castiel et. al. discloses the use of ascorbyl glucoside in skin care compositions to increase epidermal lipogenesis.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, a retinoid, and a carrier and Castiel et. al. discloses that the use of ascorbyl glucoside in skin care compositions increases epidermal lipogenesis.

Therefore, one of ordinary skill in the art would have reasonably expected that the use ascorbyl glucoside in a skin care composition comprising hexamidine, a retinoid and a carrier would result in substantially similar or improved skin care composition.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted January 8, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that claim 25 possesses written description in the parent application 10/379252 and is thus entitled to an effective filing date of March 4, 2003. However, Castiel et al. was filed on January 13, 2003, which is before the effective filing date of the instant claims. Furthermore it is a continuation of application 09/828884, which was filed on April 10, 2001. Therefore Castiel et al. is still prior art under 35 USC 102(e).

In addition, Applicant argues that Castiel et al. does not address the combination of hexamidine and vitamin B3 as discussed above with regard to claim 1. Applicant's arguments are the same as those made with respect to Jensen et al. in view of Flick et al. in view of Gensler et al. in view of Oblong et al. above, and are found not persuasive for the same reasons. Therefore the rejection is deemed proper and maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 23, 26, 31, 35, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 11, 12, and 20 of U.S. Patent No. 10/841193. (Published as US publication 2004/0228820, cited in PTO-892, commonly assigned with the instant application, herein referred to as '193) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 and 11-18 of '193 anticipate or render obvious the claimed invention.

Claims 1 and 4 of '193 are drawn to a skin care composition containing 0.001% to about 10% of an amidine. Claim 3 defines the amidine as hexamidine with an alkane polyol that is reasonably considered to be a dermatologically acceptable carrier. Claims 11 and 12 of '193 further comprise additional skin care ingredients including BHT, phytosterols, a vitamin B_3 compound, panthenol, and retinoids. Claim 20 of '193 is drawn to a composition that is a water in silicone emulsion. With regard to the specific amount of vitamin B3 in instant claim 26, it would have been obvious to one of ordinary skill in the art to choose an appropriate amount of active agent. Therefore claims 1, 3, 4, 11, 12, and 20 of '193 anticipate or render obvious the claimed invention.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the

provisional rejection be held in abeyance until the application '193 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained.

Claims 1-5, 21-24, 31, 32, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-13, and 18 of copending Application No. 10/977848. (Published as US patent publication 2005/0214332, cited in PTO-892, herein referred to as '848) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 5-13, and 18 of '848 anticipate the claimed invention.

Claim 1 of '848 is drawn to a composition comprising at least two skin care active compounds including sugar amines, vitamin B3 compounds, phytosterols, and hexamidines. Dependent claims 5-13 specify that the compounds include N-acetyl glucosamine and niacinamide, and that he composition is an oil-in-water or silicone-in-water emulsion. Claim 18 is drawn to a composition further including retinoids, peptides, and butylated hydroxytoluene (the compound of instant claim 36) With regard to the specific amount of vitamin B3 in instant claim 26, it would have been obvious to one of ordinary skill in the art to choose an appropriate amount of active agent. Therefore claims 1, 5-13, and 18 of '848 anticipate or render obvious the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the provisional rejection be held in abeyance until the application '848 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained.

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, and 4-16 of copending Application No. 10/152,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '924 application is directed to an article comprising a skin care composition comprising hexamidine, niacinamide (vitamin B3) and a carrier. The claims herein are directed to a composition comprising hexamidine, vitamin B3 and a carrier. Thus, claims 1-3 are deemed anticipated by claims 1-2 and 4-16 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the provisional rejection be held in abeyance until the application '924 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
3/7/2009